

U.S.S.N. 10/691,928  
Filed: October 23, 2003

**AMENDMENT AND RESPONSE TO OFFICE ACTION**

**Amendment**

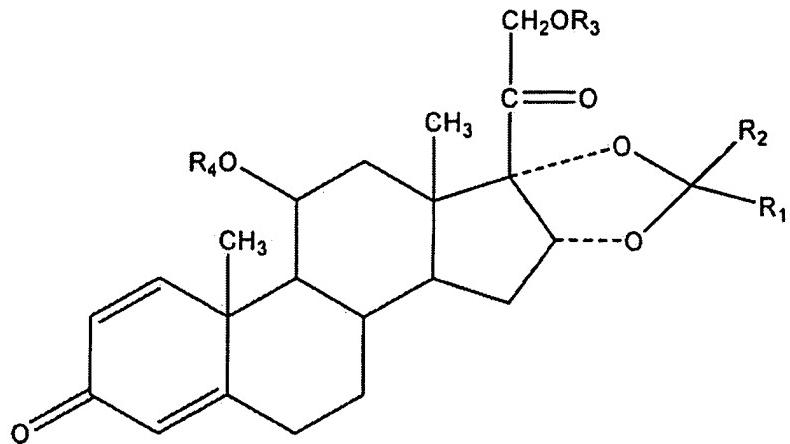
**In the Claims**

1. (currently amended) A topical antifungal composition comprising:
  - a) a therapeutically effective amount of an antifungal compound for treating a fungal disease or a pharmaceutically acceptable salt thereof; and
  - b) a therapeutically effective amount of a low to low-medium potency steroidal anti-inflammatory causing minimal skin atrophy, striae and hypopigmentation, in a concentration between 0.01 wt% and 5.0 wt%, and having a higher potency than 1 wt% hydrocortisone, and
  - c) a carrier suitable for administration of the antifungal compound and the steroidal anti-inflammatory to the skin, wherein the composition does not cause the steroids to penetrate the skin and cause undesirable local side effects.
2. (previously presented) The antifungal composition of claim 1 wherein the steroidal anti-inflammatory has the following structure:

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wherein R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, and R<sub>4</sub> taken independently can be H, C1-C10 alkyl, C1-C10 alkenyl, C3-C10 cycloalkyl, and phenyl groups; R<sub>1</sub> and R<sub>2</sub> taken together can be C3-C10 cycloalkyl; and R<sub>3</sub> and R<sub>4</sub> taken independently can be H, C1-C10 alkyl, C1-C10 alkenyl, C3-C10 cycloalkyl, phenyl, C7-C10 phenylalkyl, carboxylate, sulfonyl, phosphoryl, and phosphonyl groups.

3. (currently amended) The composition of claim 1 wherein R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, and R<sub>4</sub> groups are independently H, CH<sub>3</sub>, ethyl, propyl, phenyl, and phenylmethyl groups.

4. (currently amended) The composition of claim 2 wherein the steroidal anti-inflammatory is desonide and the antifungal compound is clotrimazole.

5. (currently amended) The composition of claim 4 containing 0.01 wt % to 5.0% wt % desonide.

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6. (original) The composition of claim 5 containing 0.1 wt % to 5 wt % clotrimazole.
7. (previously presented) The composition of claim 1 wherein the steroidal anti-inflammatory is selected from the group consisting of Fluocinolone acetonide, Hydrocortisone valerate, Hydrocortisone butyrate, Alclometasone dipropionate, Desonide, and hydrocortisone probutate.
8. (original) The composition of claim 1 wherein the antifungal is selected from the group consisting of polyene type antifungal agents and azole type antifungal agents.
9. (original) The composition of claim 8 wherein the antifungal is selected from the group consisting of Amphoterican B, Nystatin, Flucytosin, Natamycin, Ketoconazole, Econoazole, Miconazole, Itraconazole, Fluconazole, Econazole, Clotrimazole, Griseofulvin, Oxiconazole, Terconazole, Tioconazole, Clotrimazole, Silver Sulfadiazine, Ciclopirox olamine, and Terbinafine.
10. (original) The composition of claim 1, wherein the composition is formulated as a cream, ointment, gel, lotion, foam, powder, aerosol, spray, shampoo, or liquid solution.
11. (original) The composition of claim 10 having a pH of about 3.5 to about 7.0 further comprising: at least one solvent, at least one emollient, at least one humectant, at least one preservative, and at least one emulsifier; and optionally including an acid, base, or buffering agent to adjust the pH.

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12. (original) The composition of claim 11, wherein the solvent is selected from the group consisting of propylene glycol, butylene glycol, hexylene glycol, polyethylene glycols, polypropylene glycols, and polyurethane compounds; the emollient is selected from the group consisting of white petrolatum, mineral oil, propylene glycol dicaprylate, lower fatty acid esters and lower alkyl ethers of propylene glycol, cetyl alcohol, cetostearyl alcohol, stearyl alcohol, stearic acid, cetyl esters wax, spermaceti wax, and white wax; the humectant is selected from the group consisting of glycerin and sorbitol; and the emulsifier is selected from the group consisting of glycetyl monostearate, glycetyl monoleate, stearic acid, polyoxyethylene cetyl ether, polyoxyethylene cetostearyl ether, polyoxyethylene stearyl ether, and polyethylene glycol stearate; wherein the optional acid is selected from the group consisting of hydrochloric acid and phosphoric acid, the optional base is chosen from diethanolamine, triethanolamine, and sodium hydroxide, the optional buffering agent is chosen from monobasic sodium phosphate and dibasic sodium phosphate, and the preservative is chosen from benzyl alcohol, sodium benzoate and parabens.

13. (original) The composition of claim 1 wherein the antifungal is in an amount effective to treat fungal disease selected from the group consisting of tinea pedis, tinea capitis, tinea corporis, tinea versicolor, scalp disorders, tinea cruris, and candidiasis.

14. (previously presented) A method of treating a fungal disease comprising administering to a subject in need of treatment the composition of any of claim 1-13 or 17, with a thin application of the composition two times per day to the affected areas.

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15. (original) The method of claim 14 wherein the subject is a child of under 10 years old.
16. (original) The method of claim 14 wherein the fungal disease is selected from the group consisting of tinea pedis, tinea capitis, tinea corporis, tinea versicolor, scalp disorders, tinea cruris, and candidiasis.
17. (previously presented) The composition of claim 1 wherein the steroidal anti-inflammatory is not halogenated.